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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,659	05/17/2001	Erik D'Hondt	B45160	2240

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EXAMINER

SCHEINER, LAURIE A

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,659

Applicant(s)

D'Hondt, E.

Examiner

Laurie Scheiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 10, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above, claim(s) 22-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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Applicant's traversal of the outstanding lack of unity of invention. The examiner asserts that the claims of Group II do not share the special technical feature of Group I since claims 22-39 are drawn to various compounds and corresponding compositions containing said respective various compounds, and the compounds and compositions are therefore produced by more than a single method. Thus, properly grouping together the inactivated virus and virus containing vaccine necessarily results in the restriction of groups as set forth in Paper No. 6. That is, applicant properly points out and correctly argues that unity exists between a compound and a composition comprising that compound. The virus and vaccine are inexorably linked; group II therefore comprises more than one compound and/or composition, in contrast to a first sole compound (which would require that a first compound or composition be grouped with the corresponding first method of making. In short, grouping of the virus and vaccine as one takes precedence over the separation of the compound and composition, resulting in the grouping of inactivated virus and method of making as one. The requirement for unity of invention under 37 CFR 1.499 is maintained. Claims 17-21 are considered below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-21 are rejected under 35 U.S.C.103(a) as being unpatentable over Robertson et al. (US Patent 5,268,292) in view of Bishop et al. (Journal of Virological Methods, 47 (1994) 203-216) and Andre et al. (Prog. Med. Virol. Basel, Karger, 1990, vol. 37, pp. 72-95).

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Robertson et al. teach, subsequent to cell harvest, a method requiring trypsin treatment for purification of HAV (column 5, lines 57-59) which results in a virus preparation lacking cellular protein contaminants (Fig. 2B). That is, Robertson et al. disclose the purification of Hepatitis A virus (HAV) by a method that comprises harvesting of virus from cell lysates and treatment with trypsin to degrade protein contaminants. The resulting viral preparation is highly purified and cellular protein contaminants cannot be detected in polyacrylamide gel electrophoresis. HAS-15 is exemplified, however, HM-175 is mentioned as an example of a functionally equivalent cytopathic isolate.

Robertson et al. fail to teach the inactivation of the viral isolate.

Bishop et al. clearly teach the inactivation of an HAV isolate (cytopathic HM-175) for purposes of vaccine production.

Andre et al. teach at page 75, under Purification, submitting partially purified HAV suspension to gel permeation chromatography, and ion-exchange chromatography; resulting in an extensively purified virus (HM-175). Inactivation of said virus is also disclosed.

It would have been obvious to one of ordinary skill in the art to have inactivated a cytopathic HAV of Robertson et al. since Bishop et al. and Andre et al. are cumulative in teaching advantages of inactivating HAV for use as vaccine. That is, Bishop et al. describe the rapid and efficient purification of HAV by a method that comprises a trypsin digestion step to separate the virus from cells. The method yields a pure preparation of virus that can be inactivated to prepare a vaccine. The additional chromatographic steps as claimed would have been obvious based on the teachings of the need to remove impurities from the virus preparation, and known chromatography provides a classical means for achieving this result.

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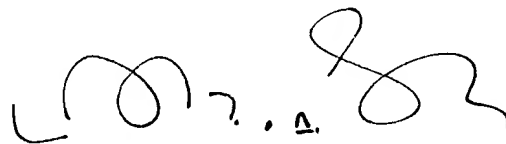
Andre et al's. teaching clearly provides motivation for the further purification of partially purified HAV suspension.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.


Laurie Scheiner/LAS
May 2, 2003


LAURIE SCHEINER
PRIMARY EXAMINER